

The management system of

Intersurgical Ltd

Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 28 August 2015 until 26 November 2019
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 02 October 2017


Issue 26. Certified since 11 January 1995

Certification is based on reports numbered GB/PC-04303

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

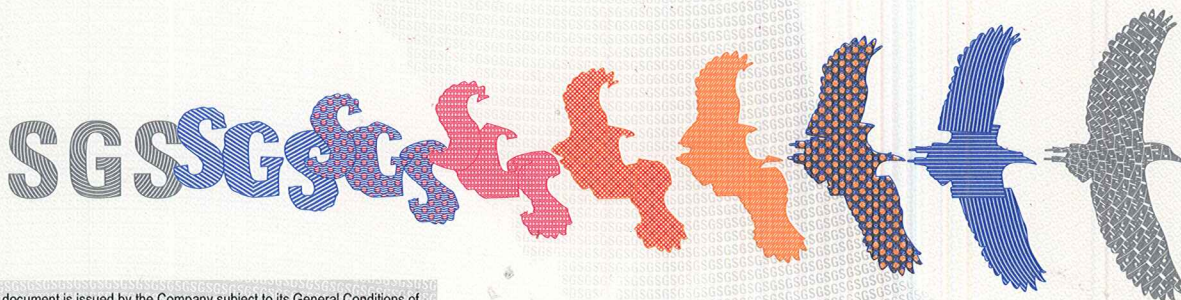


SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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Intersurgical Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 26

Detailed scope

Non sterile medical devices:

- For Airway Management: connectors, breathing filters, heat and moisture exchangers, heat and moisture exchanging filters.
- For Anaesthesia: Breathing systems, carbon dioxide absorbents, catheter mounts, connectors, breathing filters, heat and moisture exchanging filters, masks and attachments, monitoring and pressure lines and filters, reservoir bags, resuscitation systems and masks, tubing and attachments, valves - directional, positive end expiratory pressure, pressure limiting, and exhalation.
- For Critical Care: breathing filters, breathing systems, catheter mounts, connectors, heat and moisture exchangers, heat and moisture exchanging filters, heated wire breathing systems and attachments, humidification chambers, lung volume recruitment systems, masks and attachments, monitoring and pressure lines and filters, oral care treatment - suction and irrigation toothbrushes and kits, resuscitation systems and masks, suction devices – tubing and wands, tubing and attachments, valves - directional, positive end expiratory pressure, pressure limiting and exhalation, venturi valves for oxygen therapy, electrically powered moisture condenser for breathing systems
- For Oxygen and Aerosol Therapy: connectors, masks and attachments, nasal cannulae, nebulisers and nebuliser systems, tubing and attachments, water traps.

Sterile medical devices:

- For Airway Management: airways, bougies and stylets, connectors, breathing filters, heat and moisture exchangers, heat and moisture exchanging filters.
- For Anaesthesia: breathing filters, breathing systems, catheter mounts, connectors, heat and moisture exchanging filters, masks and attachments.
- For Critical Care: breathing filters, breathing systems, catheter mounts, connectors, endotracheal closed suction systems, heat and moisture exchangers, heat and moisture exchanging filters, heated wire breathing systems and attachments, humidification chambers, suction devices – tubing, water for oral rinsing.
- For Oxygen and Aerosol Therapy: connectors.

Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

- For Airway Management: guedel airways.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

UAB „INTERSURGICAL“, Armoniu g. 60/28 - 1, LT-18170 Pabradė, Lithuania

Intersurgical Limited, Circuit House, Pitronnerie Road Industrial Estate,
St Peter Port, Guernsey, GY1 2RL, UK